REMARKS

The examiner has rejected claims 39-61 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response to this rejection applicant has amended the claims to more particularly define the invention taking into consideration the examiner's comments on pages 2-3 of the office action.

Claim 62 replaces claim 39. The examiner notes in his comments concerning claim 39 that the phrase "selected from the group consisting of" in lines 7-10 is improper because there is only one Markush member (b). Applicant submits that the corresponding phrase in claim 62 is a proper expression since it refers to a Markush group of fatty acids. There are clearly many different fatty acids which fall within the defined group.

The examiner also notes with respect to claim 39 that R_3 has already an acyl chain which has 6-24 carbon atoms and questions whether this expression means "that additional fatty acids with 6-24 carbon atoms is bonded to the already existing carbon chain". Applicant submits that claim 62 avoids any confusion in this regard. It is clear from claim 62 that the composition requires one or more substances selected from the group consisting of monoglyceride preparations having the defined formula **together with** one or more substances selected from the group consisting of fatty acids which have defined characteristics. In other words the composition includes a monoglyceride component and a fatty acid component.

With respect to the examiner's criticism concerning the phrase "may contain" it is to be noted that none of the claims presently include this language.

The examiner also notes that the meaning of "a)" and "b0" in the expression "wherein the percentage of monoglyceride a) in fatty acid b0" is unclear. The confusing terms "a)" and "b0" have been omitted in claim 62 (and also in claim 63 which replaces claim 54).

The examiner notes that the expression "an antigen or vaccine that is selected from the group consisting of antigens and vaccines relevant to humans and animals" is confusing in claims 46 and 54. Claim 46 has been cancelled and this expression is not contained in claim 63 which replaces claim 54.

Claim 48 has been amended taking into consideration the examiner's comments on page 3 of the office action. Applicant submits that claim 48 now contains proper Markush terminology.

The examiner's comments concerning indefiniteness of claim 50 is now moot in view of the cancellation of this claim.

Claim 53 has been amended to correct the defects noted by the examiner on page 3 of the office action. In this regard it is to be noted that in original claim 53 the 90 grams of antigen or vaccine component was given in relation to 100 grams of the final composition. These amounts refer to production of stock compositions, not doses to be administered. To avoid the confusion noted by the examiner, the amounts are now given in percentage.

The examiner has rejected claims 39-52 under 35 U.S.C. § 102(b) as being anticipated by Roberts. The examiner has also rejected claims 39-61 under 35 U.S.C. § 102(b) as being anticipated by WO 93/06921.

In response to these rejections applicant has amended the claims so that they now require that the defined composition is in the form of "an oil-in-water suspension or emulsion". In this regard it is to be noted that Roberts teaches how to make water-in-oil emulsions which is the opposite of the claimed oil-in-water emulsions. The water-in-oil emulsion is disclosed by Roberts are completely useless for the purpose of delivery of vaccines as a spray into the nose of mammals due to their texture. Accordingly, it is clear that Roberts does not disclose or suggest the presently claimed invention. Support in the specification for this specific limitation can be found on page 7, lines 16-22 and in the examples.

It is also clear that the colloidal particles described by WO 93/06921 do not anticipate the presently claimed invention.

In view of the above arguments and further amendment to the claims, applicant respectfully requests reconsideration and allowance of all the claims which are currently pending in the application.

Respectfully submitted,

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Date: August 17, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

40. (Amended) The adjuvant composition according to Claim [39,] 62, wherein the monoglyceride preparation content is at least 90 %.

41. (Amended) The adjuvant composition according to Claim [39,] 62 wherein the monoglyceride preparation content is at least 95%.

42. (Amended) The adjuvant composition according to Claim [39,] 62 wherein the acyl chains of the monoglyceride preparations contain 8 to 20 carbon atoms and [wherein the acyl chains may] contain one or more unsaturated or saturated bonds.

43. (Amended) The adjuvant composition according to Claim [39,] 62 wherein the acyl chains of the monoglyceride preparations contain 14 to 20 carbon atoms and [wherein the acyl chains may] contain one or more unsaturated or saturated bonds.

44. (Amended) The adjuvant composition according to Claim [39,] 62 wherein the acyl chains of the fatty acid contain 8 to 20 carbon atoms[, preferably 14 to 20 carbon atoms] and [wherein the acyl chains may] contain one or more unsaturated or saturated bonds.

45. (Amended) The adjuvant composition according to Claim [39,] 62 wherein the acyl chains of the fatty acid contain 14 to 20 carbon atoms and [wherein the acyl chains may] contain one or more unsaturated or saturated bonds.

48. (Amended) The adjuvant composition according to Claim 39, wherein the composition comprises additional pharmaceutical excipients selected from the group consisting of preservatives [and], osmotic pressure controlling agents, pH-controlling agents, organic solvents, [hydrophobic agents,] enzyme inhibitors, water absorbing polymers, [surfactants,] absorption promoters and anti-oxidative agents.

49. (Amended) The adjuvant composition according to Claim [39,] 62 wherein the composition comprises additional adjuvants.

51. (Amended) The adjuvant composition according to Claim [50,] 62 wherein the composition is in a form suitable for administration to the mucosa of the nose, mouth, vagina, rectum or the intestine.

52. (Amended) The adjuvant composition according to Claim [50,] 51 wherein the composition is in a form suitable for administration to the mucosa of the nose.

53. (Amended) A vaccine or antigen composition, [containing in 100 g of the final composition:] wherein the final composition contains:

from 0.01 to 90 [g of a antigen or vaccine] % of the antigen/vaccine component

from [1 to 20 g] 0.1 to 20% of a monoglyceride

from [1 to 20 g] 0.1 to 20% of a fatty acid

from 0.01 to 99 [g] % of water

from 0.01 to 99 [g] % of PBS or saline

and optionally one or more additional adjuvant or excipient.

55. (Amended) The vaccine or antigen composition according to Claim [54,] 63 wherein the monoglyceride preparation content is at least 90 %.

57. (Amended) The vaccine or antigen composition according to Claim [54,] 63 wherein the acyl chains of the monoglyceride preparations contain 8 to 20 carbon atoms, and [wherein the acyl chains may] contain one or more unsaturated or saturated bonds.

58. (Amended) The vaccine or antigen composition according to Claim 57, wherein the acyl chains of the monoglyceride preparations contain 14 to 20 carbon atoms and [where the acyl chains may] contain one or more unsaturated or saturated bonds.

59. (Amended) The vaccine or antigen composition according to Claim [54,] 63 wherein the acyl chains of the fatty acid contain 8 to 20 carbon atoms and [where the acyl chains may] contain one or more unsaturated or saturated bonds.

60. (Amended) The vaccine or antigen composition according to Claim 59, wherein the acyl chains of the fatty acid contain 14 to 20 carbon atoms and [where the acyl chains may] contain one or more unsaturated or saturated bonds.